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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

LOEB, BRONWEN

ART UNIT PAPER NUMBER

1636

DATE MAILED: 02/26/2003

16

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/743,394

Applicant(s)

DORKEN ET AL.

Examiner

Bronwen M. Loeb

Art Unit

1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 04 December 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 2-6,9 and 11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 4,6,9 and 11 is/are rejected.
- 7) ☐ Claim(s) 2,3 and 5 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on 07 February 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

This action is in response to the amendment filed 4 December 2002 in which claims 2-6 and 9 were amended, claim 1 was cancelled and new claim 11 was provided.

Claims 2-6, 9 and 11 are pending.

Response to Amendment

1. The rejection of claims 1-6 and 9 under 35 U.S.C. §112, first paragraph, as containing new matter, has been withdrawn in view of Applicant's amendment.

The rejection of claims 1-6 and 9 under 35 U.S.C. §112, second paragraph, as being indefinite has been withdrawn in view of Applicant's amendment.

2. New grounds of rejection, necessitated by Applicant's amendment, are set forth below.

New Grounds of Rejection

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. §102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 4, 6, 9 and 11 are rejected under 35 U.S.C. §102(b) as being anticipated by Nabel et al (USP 5,863,904).

Nabel et al teach transferring the cDNA for p21 into cell lines. The expression vectors encoding p21 can be eukaryotic and viral vectors, including adenovirus vectors, and can addition contain regulatory elements. See col. 2, line 54- col. 3, line 36. Nabel et al also teaches introducing ADV-p21, an adenoviral vector comprising a p21 coding sequence, into 293 cells for propagating and obtaining viruses, which includes an Ad vector, in col. 6, lines 21-34. Expression of the p21 coding sequence is controlled by the Rous sarcoma virus (RSV) promoter. The 293 cells are able to express p21 from the RSV promoter in a eukaryotic expression plasmid (see col. 10, lines 19-22). It is therefore expected that it could express p21 transiently from the RSV promoter in ADV-p21 during the propagation of virus in the 293 cells.

Allowable Subject Matter

5. It is noted that upon further consideration and Applicant's persuasive argument regarding the p21 coding sequence being on a different DNA than the Ad vector, the embodiment of claim 11, and its dependent claims, and of claim 9, wherein the Ad vector does not comprise the p21 coding sequence is allowable subject matter.

6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Bruder et al (USP 6,391,612 B1) teaches a method for propagation of viral eukaryotic gene transfer vectors that comprise a deleterious gene in a host cell wherein the host cell comprises a "blocking gene". The blocking gene inhibits the adverse effects of the deleterious gene on the host cell. The result is

improved yield of the viral vector. Bruder et al does not teach or suggest using p21 (also known as CIP1, WAF1 or sdi1) as the blocking gene in their method.

Conclusion

Claims 4, 6, 9 and 11 are rejected. Claims 2, 3 and 5 are objected to as being dependent on a rejected claim.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Certain papers related to this application may be submitted to Art Unit 1636 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone numbers for the Group are (703) 308-4242 and (703) 305-3014. NOTE: If Applicant does submit a

Art Unit: 1636

paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bronwen M. Loeb whose telephone number is (703) 605-1197. The examiner can normally be reached on Monday through Friday, from 11:00 AM to 7:30 PM. A phone message left at this number will be responded to as soon as possible (usually no later than the next business day after receipt by the examiner).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Remy Yucel, can be reached on (703) 305-1998.

The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Bronwen M. Loeb, Ph.D.
Patent Examiner
Art Unit 1636

February 23, 2003



REMY YUCEL, PH.D
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